

Notice of Allowability

Application No.

09/931,402

Applicant(s)

BROWNING ET AL.

Examiner

Christopher H. Yaen

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1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 1/25/2005.
2. ☒ The allowed claim(s) is/are 7-17,38-49,61-89 and 91-163.
3. ☒ The drawings filed on 16 August 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/875,560.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit
of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☐ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

Jeffrey Siew
JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
4/17/05

Christopher Yaen
Art Unit 1642

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Amy Mandragouras on 4/15/2005.

The application has been amended as follows:

7. (Currently Amended) A method for treating or reducing the advancement, severity or effects of neoplasia comprising administering a therapeutically effective amount of at least two compositions, each composition comprising at least one anti-LT- β -R antibody and a pharmaceutically acceptable carrier, wherein each anti-LT- β -R antibody is directed to a different epitope.

8. (Previously presented) The method according to claim 7, wherein one anti-LT β -R is CBE11.

9. (Currently Amended) The method according to claim 7, ~~comprising at least two~~ wherein the anti-LT- β -R monoclonal antibodies ~~which~~ are directed against non-overlapping epitopes of LT- β -R.

10. (Original) The method according to claim 9, wherein one anti-LT- β -R monoclonal antibody is selected from the group consisting of AGH1 and BDA8, and another anti-LT- β -R monoclonal antibody is selected from the group consisting of BCG6, BHA10, BKA11, CDH10 and CBE11.

11. (Original) The method according to claim 9, wherein one anti-LT- β -R monoclonal antibody is selected from the group consisting of BCG6 and BHA10, and another anti-LT- β -R monoclonal antibody is selected from the group consisting of AGH1, BDA8, BKA11, CDH10, and CBE11.

12. (Original) The method according to claim 9, wherein one anti-LT- β -R monoclonal antibody is selected from the group consisting of BKA11 and CDH10, and

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another anti-LT- β -R monoclonal antibody is selected from the group consisting of AGH1, BDA8, BCG6, BHA10, and CBE11.

13. (Original) The method according to claim 9, wherein one anti-LT- β -R monoclonal antibody is CBE11, and another anti-LT- β -R monoclonal antibody is selected from the group consisting of AGH1, BDA8, BCG6, BHA10, BKA11, CDH10 and CBE11.

14. (Previously presented) The method according to claim 9, wherein at least one anti-LT- β -R monoclonal antibody is CBE11 and at least one anti-LT- β -R monoclonal antibody is BHA10.

15. (Previously presented) The method according to claim 9, wherein at least one anti-LT- β -R monoclonal antibody is CBE11 and at least one anti-LT- β -R monoclonal antibody is CDH10.

16. (Previously presented) The method according to claim 9, wherein at least one anti-LT- β -R monoclonal antibody is AGH1 and at least one anti-LT- β -R monoclonal antibody is CDH10.

17. (Previously presented) The method according to claim 7, further comprising administering IFN- γ .

18-37. (Canceled)

38. (Currently Amended) A pharmaceutical composition comprising a therapeutically effective amount of at least two anti-LT- β -R antibodies, and a pharmaceutically acceptable carrier, wherein each anti-LT- β -R antibody is directed to a different epitope.

39. (Previously presented) The pharmaceutical composition according to claim 38, wherein at least one anti-LT- β -R antibody is a monoclonal antibody.

40. (Original) The pharmaceutical composition according to claim 39, wherein the anti-LT- β -R antibody is CBE11.

41. (Currently Amended) The pharmaceutical composition according to claim 38, wherein ~~at least two~~ the anti-LT- β -R antibodies are directed against non-overlapping epitopes of LT- β -R.

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42. **(Original)** The pharmaceutical composition according to claim 41, wherein one anti-LT- β -R monoclonal antibody is selected from the group consisting of AGH1 and BDA8, and another anti-LT- β -R monoclonal antibody is selected from the group consisting of BCG6, BHA10, BKA11, CDH10 and CBE11.

43. *(Currently Amended)* The pharmaceutical composition according to claim 41, wherein one anti-LT- β -R monoclonal antibody is selected from the group consisting of BCG6 and BHA10, and another anti-LT- β -R monoclonal antibody is selected from the group consisting of AGH1, BDA8, CKA11, CDH10 and CBE11.

44. **(Original)** The pharmaceutical composition according to claim 41, wherein one anti-LT-B-R monoclonal antibody is selected from the group consisting of BKA11 and CDH10, and another anti-LT-B-R monoclonal antibody is selected from the group consisting of AGH1 and BDA8, BCG6, BHA10 and CBE11.

45. **(Original)** The pharmaceutical composition according to claim 41, wherein the anti-LT- β -R monoclonal antibody is CBE11, and another anti-LT- β -R monoclonal antibody is selected from the group consisting of AGH1, BDA8, BCG6, BHA10, BKA11, CDH10, and CBE11.

46. **(Previously presented)** The pharmaceutical composition according to claim 41, wherein at least one anti-LT- β -R monoclonal antibody is CBE11 and at least one anti-LT-B-R monoclonal antibody is BHA10.

47. **(Previously presented)** The pharmaceutical composition according to claim 41, wherein at least one anti-LT- β -R monoclonal antibody is CBE11 and at least one anti-LT- β -R monoclonal is CDH10.

48. **(Previously presented)** The pharmaceutical composition according to claim 41, wherein at least one anti-LT- β -R monoclonal antibody is AGH1 and at least one anti-LT- β -R monoclonal antibody is CDH10.

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49. **(Currently amended)** The pharmaceutical composition according to claim 41 ~~any one of the claims 41-48~~, further comprising IFN- γ .

Claims 50-60 (Canceled)

61. **(Previously presented)** The method according to claim 7, wherein at least one anti-LT- β -R antibody has the same epitope specificity as an antibody produced by cell line CB.E11.1, ATCC accession number HB11793.

62. **(Previously presented)** The method according to claim 7, wherein at least one anti-LT- β -R antibody has the same epitope specificity as an antibody produced by cell line BH.A10, ATCC accession number HB 11795.

63. **(Currently Amended)** The method according to claim 9, wherein at least one anti-LT- β -R antibody has the same epitope specificity as an antibody produced by cell line CB.E11.1, ATCC accession number HB 11793.

64. **(Previously presented)** The method according to claim 9, wherein at least one anti-LT- β -R antibody has the same epitope specificity as an antibody produced by cell line BH.A10, ATCC accession number HB 11795.

65. **(Previously presented)** The method according to claim 64, further comprising at least one anti-LT- β -R antibody having the same epitope specificity as an antibody produced by cell line CB.E11.1, ATCC accession number HB11793.

66. **(Previously presented)** The pharmaceutical composition according to claim 38, wherein the anti-LT- β -R antibody has the same epitope specificity as an antibody produced by cell line CB.E11.1, ATCC accession number HB11793.

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67. **(Previously presented)** The pharmaceutical composition according to claim 38, wherein the anti-LT- β -R antibody has the same epitope specificity as an antibody produced by cell line BH.A10, ATCC accession number HB11795.

68. **(Currently amended)** The pharmaceutical composition according to claim 41 ~~46~~, wherein at least one anti-LT- β -R antibody has the same epitope specificity as an antibody produced by cell line CBE11.1, ATCC accession number HB11793.

69. **(Currently amended)** The pharmaceutical composition according to claim 41 ~~46~~, wherein at least one anti-LT- β -R antibody has the same epitope specificity as an antibody produced by cell line BH.A10, ATCC accession number HB11795.

70. **(Previously presented)** The pharmaceutical composition according to claim 69, further comprising at least one anti-LT- β -R antibody having the same epitope specificity as an antibody produced by cell line CB.E11.1, ATCC accession number HB11793.

71. **(Previously presented)** The method according to claim 7, wherein the anti-LT- β -R antibody comprises CDRs from antibody CBE11 produced by hybridoma CB.E11.1 (ATCC Accession No. HB11793).

72. **(Previously presented)** The method according to claim 7, wherein the anti-LT- β -R antibody is selected from the group consisting of CBE11 produced by hybridoma CB.E11.1 (ATCC Accession No. HB11793), BKA11 produced by hybridoma BK.A11.AC10 (ATCC Accession No. HB11799), CDH10 produced by hybridoma CD.H10.1 (ATCC Accession No. HB11797), BCG6 produced by hybridoma BC.G6.AF5 (ATCC Accession No. HB11794), BHA10 produced by hybridoma BH.A10 (ATCC Accession No. HB11795), and AGH1 produced by hybridoma AG.H1.5.1 (ATCC Accession No. HB11796).

73. **(Previously presented)** The method according to claim 7, wherein at least one anti-LT- β -R antibody is a F(ab)₂.

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74. **(Currently amended)** The method according to claim ~~any one of claims 7, 61-65, 71, and 73~~, wherein at least one anti-LT- β -R antibody is a chimeric antibody.
75. **(Currently amended)** The method according to claim ~~any one of claims 7, 61-65, 71, and 73~~, wherein at least one anti-LT- β -R antibody is a humanized antibody.
76. **(Currently amended)** The method according to claim ~~any one of claims 7, 61-65, 71, and 73-75~~, further comprising administering an anti-tumor therapy.
77. **(Previously presented)** The method according to claim 76, wherein the anti-tumor therapy is radiation or chemotherapy.
78. **(Currently amended)** The method according to claim ~~any one of claims 7, 61-65, 71, and 73-75~~, further comprising administering an LT- β R activating agent comprising selected from the group consisting of either IFN- α , or TNF, and interferon inducing agents.
79. **(Currently amended)** The pharmaceutical composition according to claim ~~any one of claims 38, 39, and 66-70~~, wherein the anti-LT- β -R antibody is a chimeric antibody.
80. **(Currently amended)** The pharmaceutical composition according to claim ~~any one of claims 38, 39, and 66-70~~, wherein the anti-LT- β -R antibody is a humanized antibody.
81. **(Currently amended)** The pharmaceutical composition according to claim ~~any one of claims 38, 39, and 66-70~~, wherein the anti-LT- β -R antibody is a F(ab)₂.
82. **(Currently amended)** A method for treating or reducing the advancement, severity or effects of neoplasia comprising administering an effective amount of a pharmaceutical composition comprising an anti-LT- β -R antibody and a pharmaceutically acceptable carrier, wherein the composition is administered in the presence of an exogenous LT- β -R activating agent selected from the group consisting of IFN- α , TNF, ~~an interferon inducing~~

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agent, and an anti-LT- β -R antibody.

83. **(Previously presented)** The method according to claim 82, wherein the anti-LT- β -R antibody has the same epitope specificity as an antibody produced by cell line CB.E11.1, ATCC accession number HB11793.

84. **(Previously presented)** The method according to claim 82, wherein the anti-LT- β -R antibody has the same epitope specificity as an antibody produced by cell line BH.A10, ATCC accession number HB 11795.

85. **(Previously presented)** The method according to claim 82, wherein the anti-LT- β -R antibody comprises CDRs from antibody CBE11 produced by hybridoma CB.E11.1, ATCC Accession No. HB11793.

86. **(Previously presented)** The method according claim 82, wherein the anti-LT- β -R antibody is selected from the group consisting of CBE11 produced by hybridoma CB.E11.1 (ATCC Accession No. HB11793), BKA11 produced by hybridoma BK.A11.AC10 (ATCC Accession No. HB11799), CDH10 produced by hybridoma CD.H10.1 (ATCC Accession No. HB11797), BCG6 produced by hybridoma BC.G6.AF5 (ATCC Accession No. HB11794), BHA10 produced by hybridoma BH.A10 (ATCC Accession No. HB11795), and AGH1 produced by hybridoma AG.H1.5.1 (ATCC Accession No. HB11796).

87. **(Currently amended)** The method according to claim 82 ~~any one of claims 82-86~~, wherein the anti-LT- β -R antibody is a F(ab)2.

88. **(Currently amended)** The method according to claim 82 ~~any one of claims 82-86~~, wherein the anti-LT- β -R antibody is a chimeric antibody.

89. **(Currently amended)** The method according to claim 82 ~~any one of claims 82-86~~, wherein the anti-LT- β -R antibody is a humanized antibody.

90. **(Canceled)**

91. **(Currently amended)** The method according to claim 82 ~~any one of claims 82-86~~,

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further comprising administering an anti-tumor therapy.

92. **(Previously presented)** The method according to claim 91, wherein the anti-tumor therapy is radiation or chemotherapy.

93. **(Currently amended)** The method according to claim ~~any one of claims 7, 61-65, 71, 73,~~ wherein at least one anti-LT- β -R antibody is a multivalent antibody.

94. **(Currently amended)** The method according to claim 82 ~~any one of claims 82-86,~~ wherein the anti-LT- β -R antibody is a multivalent antibody.

95. **(New)** The method according to claim 61, wherein at least one anti-LT- β -R antibody is a chimeric antibody.

96. **(New)** The method according to claim 62, wherein at least one anti-LT- β -R antibody is a chimeric antibody.

97. **(New)** The method according to claim 63, wherein at least one anti-LT- β -R antibody is a chimeric antibody.

98. **(New)** The method according to claim 64, wherein at least one anti-LT- β -R antibody is a chimeric antibody.

99. **(New)** The method according to claim 65, wherein at least one anti-LT- β -R antibody is a chimeric antibody.

100. **(New)** The method according to claim 71, wherein at least one anti-LT- β -R antibody is a chimeric antibody.

101. **(New)** The method according to claim 61, wherein at least one anti-LT- β -R antibody is a humanized antibody.

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102. (New) The method according to claim 62, wherein at least one anti-LT- β -R antibody is a humanized antibody.
103. (New) The method according to claim 63, wherein at least one anti-LT- β -R antibody is a humanized antibody.
104. (New) The method according to claim 64, wherein at least one anti-LT- β -R antibody is a humanized antibody.
105. (New) The method according to claim 65, wherein at least one anti-LT- β -R antibody is a humanized antibody.
106. (New) The method according to claim 71, wherein at least one anti-LT- β -R antibody is a humanized antibody.
107. (New) The method according to claim 61, further comprising administering an anti-tumor therapy.
108. (New) The method according to claim 62, further comprising administering an anti-tumor therapy.
109. (New) The method according to claim 63, further comprising administering an anti-tumor therapy.
110. (New) The method according to claim 64, further comprising administering an anti-tumor therapy.
111. (New) The method according to claim 65, further comprising administering an anti-tumor therapy.
112. (New) The method according to claim 71, further comprising administering an

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anti-tumor therapy.

113. (New) The method according claim 61, further comprising administering an LT- β -R activating agent comprising either IFN- α or TNF.

114. (New) The method according claim 62, further comprising administering an LT- β -R activating agent comprising either IFN- α or TNF.

115. (New) The method according claim 63, further comprising administering an LT- β -R activating agent comprising either IFN- α or TNF.

116. (New) The method according claim 64, further comprising administering an LT- β -R activating agent comprising either IFN- α or TNF.

117. (New) The method according claim 65, further comprising administering an LT- β -R activating agent comprising either IFN- α or TNF.

118. (New) The method according claim 71, further comprising administering an LT- β -R activating agent comprising either IFN- α or TNF.

119. (New) The pharmaceutical composition according claim 39, wherein the anti-LT- β -R antibody is a chimeric antibody.

120. (New) The pharmaceutical composition according claim 66, wherein the anti-LT- β -R antibody is a chimeric antibody.

121. (New) The pharmaceutical composition according claim 67, wherein the anti-LT- β -R antibody is a chimeric antibody.

122. (New) The pharmaceutical composition according claim 68, wherein the anti-LT- β -R antibody is a chimeric antibody.

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123. (New) The pharmaceutical composition according to claim 69, wherein the anti-LT- β -R antibody is a chimeric antibody.

124. (New) The pharmaceutical composition according to claim 70, wherein the anti-LT- β -R antibody is a chimeric antibody.

125. (New) The pharmaceutical composition according to claim 39, wherein the anti-LT- β -R antibody is a humanized antibody.

126. (New) The pharmaceutical composition according to claim 66, wherein the anti-LT- β -R antibody is a humanized antibody.

127. (New) The pharmaceutical composition according to claim 67, wherein the anti-LT- β -R antibody is a humanized antibody.

128. (New) The pharmaceutical composition according to claim 68, wherein the anti-LT- β -R antibody is a humanized antibody.

129. (New) The pharmaceutical composition according to claim 69, wherein the anti-LT- β -R antibody is a humanized antibody.

130. (New) The pharmaceutical composition according to claim 70, wherein the anti-LT- β -R antibody is a humanized antibody.

131. (New) The pharmaceutical composition according to claim 39, wherein the anti-LT- β -R antibody is a F(ab)₂.

132. (New) The pharmaceutical composition according to claim 66, wherein the anti-LT- β -R antibody is a F(ab)₂.

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133. (New) The pharmaceutical composition according to claim 67, wherein the anti-LT- β -R antibody is a F(ab)₂.

134. (New) The pharmaceutical composition according to claim 68, wherein the anti-LT- β -R antibody is a F(ab)₂.

135. (New) The pharmaceutical composition according to claim 69, wherein the anti-LT- β -R antibody is a F(ab)₂.

136. (New) The pharmaceutical composition according to claim 70, wherein the anti-LT- β -R antibody is a F(ab)₂.

137. (New) The method according to claim 83, wherein the anti-LT- β -R antibody is a F(ab)₂.

138. (New) The method according to claim 84, wherein the anti-LT- β -R antibody is a F(ab)₂.

139. (New) The method according to claim 85, wherein the anti-LT- β -R antibody is a F(ab)₂.

140. (New) The method according to claim 86, wherein the anti-LT- β -R antibody is a F(ab)₂.

141. (New) The method according to claim 83, wherein the anti-LT- β -R antibody is a chimeric antibody.

142. (New) The method according to claim 84, wherein the anti-LT- β -R antibody is a chimeric antibody.

143. (New) The method according to claim 85, wherein the anti-LT- β -R antibody is a chimeric antibody.

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144. (New) The method according to claim 86, wherein the anti-LT- β -R antibody is a chimeric antibody.

145. (New) The method according to claims 83, wherein the anti-LT- β -R antibody is a humanized antibody.

146. (New) The method according to claims 84, wherein the anti-LT- β -R antibody is a humanized antibody.

147. (New) The method according to claims 85, wherein the anti-LT- β -R antibody is a humanized antibody.

148. (New) The method according to claims 86, wherein the anti-LT- β -R antibody is a humanized antibody.

149. (New) The method according to claim 82, further comprising administering an anti-tumor therapy.

150. (New) The method according to claim 83, further comprising administering an anti-tumor therapy.

151. (New) The method according to claim 84, further comprising administering an anti-tumor therapy.

152. (New) The method according to claim 85, further comprising administering an anti-tumor therapy.

153. (New) The method according to claim 86, further comprising administering an anti-tumor therapy.

154. (New) The method according to claim 61, wherein at least one anti-LT- β -R antibody is a multivalent antibody.

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155. (New) The method according to claim 62, wherein at least one anti-LT- β -R antibody is a multivalent antibody.
156. (New) The method according to claim 63, wherein at least one anti-LT- β -R antibody is a multivalent antibody.
157. (New) The method according to claim 64, wherein at least one anti-LT- β -R antibody is a multivalent antibody.
158. (New) The method according to claim 65, wherein at least one anti-LT- β -R antibody is a multivalent antibody.
159. (New) The method according to claim 71, wherein at least one anti-LT- β -R antibody is a multivalent antibody.
160. (New) The method according to claim 83, wherein the anti-LT- β -R antibody is a multivalent antibody.
161. (New) The method according to claim 84, wherein the anti-LT- β -R antibody is a multivalent antibody.
162. (New) The method according to claim 85, wherein the anti-LT- β -R antibody is a multivalent antibody.
163. (New) The method according to claim 86, wherein the anti-LT- β -R antibody is a multivalent antibody.
164. (New) The pharmaceutical composition according to claim 42, further comprising IFN- γ .
165. (New) The pharmaceutical composition according to claim 43, further comprising IFN- γ .

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166. (New) The pharmaceutical composition according to claim 44, further comprising IFN- γ .

167. (New) The pharmaceutical composition according to claim 45, further comprising IFN- γ .

168. (New) The pharmaceutical composition according to claim 46, further comprising IFN- γ .

169. (New) The pharmaceutical composition according to claim 47, further comprising IFN- γ .

170. (New) The pharmaceutical composition according to claim 48, further comprising IFN- γ .

All rejections and or objections are withdrawn in view of the applicant's amendments and arguments thereto as set forth in the paper filed 1/28/2005.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H. Yaen whose telephone number is 571-272-0838. The examiner can normally be reached on Monday-Friday 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher Yaen
Art Unit 1642
April 18, 2005


JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
4/17/05